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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/769,727	01/26/2001	Robert J. Ein	035887-0106	5192

7590 10/07/2003

STOLL, KEENON & PARK LLP
300 WEST VINE STREET
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LEXINGTON, KY 40507-1801

EXAMINER

JEFFERY, JOHN A

ART UNIT	PAPER NUMBER
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3742

DATE MAILED: 10/07/2003

#14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/769,727

Applicant(s)

EIN, ROBERT J.

Examiner

John A. Jeffery

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 10,12-23,25,28-32,48,49,52 and 54-68 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 12-14,19-22,25,28-31,48,49,52 and 54-67 is/are allowed.
- 6) ☒ Claim(s) 6,7,10,15-18,23,32 and 68 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☒ The proposed drawing correction filed on 09 May 2003 is: a) ☒ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Claim Objections

Claims 68, 6, 7, 10, 15-18, 23, and 28-32 are objected to because of the following informalities:

In line 10, "lamina" must be changed to "layer." Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 15, and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The test for definiteness under 35 U.S.C. § 112, second paragraph is whether "those skilled in the art would understand what is claimed when the claim is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576, 1 USPQ2d 1081, 1088 (Fed. Cir. 1986).

Here, claims 10, 15, and 16 depend from cancelled claim 8. For purposes of examination, the examiner presumes the claims were intended to depend from claim 68.

Claim Rejections - 35 USC § 103

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 68, 7, and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US6023932) or Patz et al (US5800490) in view of Sundstrom et al (US5913849). Johnston discloses a Peltier device 18 attached to the wrap adapted to be attached to the body. See Figs. 3 and 4. Note also control device in Fig. 4 and temperature sensors 40, 42 connected thereto. Also, Patz et al discloses Peltier device 85 attached to the wrap adapted to be attached to the body. See Figs. 1 and 3-11. The claims differ from the previously cited prior art in calling for the wrap comprising a laminar construction with a plurality of individual lamina disposed between, and coextensive with, inner and outer layers with a TE device mounted to the laminate at a mid-laminate position. Providing an electrical temperature control means disposed within a plurality of lamina capable of being wrapped is conventional and well known in the art as evidenced by Sundstrom et al (US5913849). Sundstrom et al (US5913849) in Fig. 1 discloses a plurality of lamina disposed between inner and outer layers 1 and 7, the interior lamina substantially coextensive with the inner and outer layers. An electrical heating device 6 is disposed within the lamina in order to provide electrically produced heat to the patient. Moreover, certain additives can be provided between

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lamina layers that have beneficial effects on the patient thus mitigating the effects of localized heating. See col. 4, lines 29-53. In view of Sundstrom et al (US5913849), it would have been obvious to one of ordinary skill in the art to provide multiple lamina between the inner and outer cover layers and dispose the electrical temperature modification device within the lamina in the previously described apparatus so that certain additives could be added to the layers between lamina thus mitigating the effects of localized heating of the tissue. With regard to the limitation that the TE device be disposed in the mid-laminate position, no criticality is seen in the disposal of the device mid-laminate as opposed to the off-center alignment of Sundstrom et al (US5913849).

Claims 68, 7, 10, 23, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762) and further in view of Sundstrom et al (US5913849). Claims 1-5, 7-10, 23, 32, 33, and 36-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Nowak (US3132688), and further in view of Patz et al (US5800490). Chapman (US3648469) discloses a flexible therapeutic heating pillow with a Peltier device therein and a control 17. The claims differ from the previously cited prior art in calling for the pillow to be adapted to be secured to a body surface. Securing therapeutic pillows to body surfaces via straps is conventional and well known in the art as evidenced by Gray (US6024762) noting the last sentence of the Abstract and Fig. 7 wherein the pillow can be secured and worn by the patient. In view of Gray (US6024762), it would have been obvious to one of ordinary skill in the art to provide

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means for securing the pillow of Chapman (US3648469) to the body so that it can be worn by the patient thereby enabling therapeutic heating/cooling to be applied to the body while performing normal daily activities. The claims also differ from the previously cited prior art in calling for the wrap comprising a laminar construction with a plurality of individual lamina disposed between, and coextensive with, inner and outer layers with a TE device mounted to the laminate at a mid-laminate position. Providing an electrical temperature control means disposed within a plurality of lamina capable of being wrapped is conventional and well known in the art as evidenced by Sundstrom et al (US5913849). Sundstrom et al (US5913849) in Fig. 1 discloses a plurality of lamina disposed between inner and outer layers 1 and 7, the interior lamina substantially coextensive with the inner and outer layers. An electrical heating device 6 is disposed within the lamina in order to provide electrically produced heat to the patient. Moreover, certain additives can be provided between lamina layers that have beneficial effects on the patient thus mitigating the effects of localized heating. See col. 4, lines 29-53. In view of Sundstrom et al (US5913849), it would have been obvious to one of ordinary skill in the art to provide multiple lamina between the inner and outer cover layers and dispose the electrical temperature modification device within the lamina in the previously described apparatus so that certain additives could be added to the layers between lamina thus mitigating the effects of localized heating of the tissue. With regard to the limitation that the TE device be disposed in the mid-laminate position, no criticality is seen in the disposal of the device mid-laminate as opposed to the off-center alignment of Sundstrom et al (US5913849).

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Claims 6, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US6023932) or Patz et al (US5800490) in view of Sundstrom et al (US5913849), and further in view of Nishida et al (US4633062). The claims differ from the previously cited prior art in calling for a pressure sensor mounted on the wrap for turning on the control unit when the sensor is activated. The use of pressure sensors as human body detection means in flexible, heated wraps is conventional and well known in the art as evidenced by Nishida et al (US4633062) noting "human body detecting means" 5 which comprises a pressure sensor (col. 4, lines 15-18) which provides a control signal to the control means for automatic temperature control. In view of Nishida et al (US4633062), it would have been obvious to one of ordinary skill in the art to use a pressure sensor in the previously described apparatus so that the presence or absence of the patient was detected via the pressure sensor thereby more accurately controlling the temperature of the patient.

Claims 6, 15, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Sundstrom et al (US5913849), and further in view of Nishida et al (US4633062). The claims differ from the previously cited prior art in calling for a pressure sensor mounted on the wrap for turning on the control unit when the sensor is activated. The use of pressure sensors as human body detection means in flexible, heated wraps is conventional and well known in the art as evidenced by Nishida et al (US4633062) noting "human body

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detecting means" 5 which comprises a pressure sensor (col. 4, lines 15-18) which provides a control signal to the control means for automatic temperature control. In view of Nishida et al (US4633062), it would have been obvious to one of ordinary skill in the art to use a pressure sensor in the previously described apparatus so that the presence or absence of the patient was detected via the pressure sensor thereby more accurately controlling the temperature of the patient.

Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnston (US6023932) or Patz et al (US5800490) in view of Sundstrom et al (US5913849) and further in view of James (US5601618). The claims differ from the previously cited prior art in calling for at least one electrode to transmit a pulse to the body surface. Providing a flexible heating pad which also functions to deliver electrical pulses to the body is conventional and well known in the art as evidenced by James (US5601618) noting col. 3, lines 16-20 where a heating pad simultaneously provides electrical pulses to the patient for stimulation as well as heating. In view of James (US5601618), it would have been obvious to one of ordinary skill in the art to provide electrical pulses in conjunction with the heating/cooling effect of the previously described apparatus so that the patient was stimulated by the same apparatus that provided heating and cooling thereby providing three therapeutic functions (i.e., heating, cooling, and stimulation) in a single pad.

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Claims 16 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chapman (US3648469) in view of Gray (US6024762), Sundstrom et al (US5913849), and further in view of James (US5601618). The claims differ from the previously cited prior art in calling for at least one electrode to transmit a pulse to the body surface. Providing a flexible heating pad which also functions to deliver electrical pulses to the body is conventional and well known in the art as evidenced by James (US5601618) noting col. 3, lines 16-20 where a heating pad simultaneously provides electrical pulses to the patient for stimulation as well as heating. In view of James (US5601618), it would have been obvious to one of ordinary skill in the art to provide electrical pulses in conjunction with the heating/cooling effect of the previously described apparatus so that the patient was stimulated by the same apparatus that provided heating and cooling thereby providing three therapeutic functions (i.e., heating, cooling, and stimulation) in a single pad.

Allowable Subject Matter

Claims 59, 12, 13, 67, 14, 19, 21, 20, 22, 60, 48, 49, 25, 61, 62, 28-31, 58, 64, 65, 52, 63, 54-57, and 66 are allowable over the art of record.

Response to Arguments

Applicant's arguments have been considered but are deemed to be moot in view of the new grounds of rejection. Although the §102(e) rejection citing Johnston has been replaced with a §103(a) rejection thus rendering moot Applicant's arguments

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pertaining to the §102(e) rejection, the examiner nevertheless feels compelled to comment on the issues raised by Applicant.

While the examiner appreciates Applicant's thorough review of the history of § 102(e) and subsequent amendments thereto via the AIPA, the examiner respectfully disagrees with Applicant's contention that Johnston does not qualify as §102(e) prior art. Applicant argues that the quoted passage in MPEP § 2132.01 is purportedly "in error" and contends that the quoted passage "...a U.S. patent published within the year prior to the application filing date..." actually refers to published U.S. patent applications -- not U.S. patents. Remarks, Page 15. Applicant then speculates that it would have "unlikely" that this section of the MPEP would have referred to U.S. patents in light of its previous discussion pertaining to "publications" and other "published" documents. Essentially, Applicant is arguing that a U.S. patent is not a "publication" in the context of MPEP § 2132.01. Therefore, according to Applicant, the passage quoted by the examiner referring to "a U.S. patent published within the year" must refer to a published application under the AIPA -- not a granted U.S. patent that confers patent rights to its owner. Remarks, P. 15.

However, the examiner respectfully disagrees. Indeed, the statute itself supports the examiner's position. 35 U.S.C. §§ 102(a) and (e) state that a person is entitled to a patent unless:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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* * *

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or **(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent**, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Because the Johnston reference is a U.S. patent document published prior to Applicant's filing date, it actually meets both 102(a) and 102(e). The reference meets 102(a) since it was patented in this country before applicant's invention. Also, it meets § 102(e) since it was a patent granted on an application for patent by another filed in the U.S. before applicant's invention.

But more importantly, there is no language in §102(e) that precludes the citation of a granted U.S. patent prior to the applicant's filing date. All that §102(e) requires is that (1) the patent is granted, and (2) the application for patent is filed in the U.S. before applicant's invention. Thus, for purposes of §102(e), the date of grant of the U.S. patent is irrelevant.¹ Indeed, if the grant date of the U.S. patent was critical in connection with §102(e) in addition to the filing date, presumably Congress would have so specified in the statute. But they did not. Indeed, Congress' intent is clear when comparing the two requirements side-by-side: the filing requirement has an express time limitation associated with it (i.e., filing must be before applicant's invention). In contrast, the grant requirement has no corresponding timing limitation.

¹ However, if the publication date of the U.S. patent is more than one year prior to Applicant's filing date, then Applicant is barred under §102(b). See 35 U.S.C. § 102(b).

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Moreover, this interpretation is consistent with the MPEP passage quoted by the examiner in the first office action. Upon issuance, U.S. patents not only confer patent rights to the patent owner, but also disclose Applicant's invention to the public as a published document available to the public. Thus, an "issued" or "granted" U.S. patent has a corresponding publication date corresponding to its date of issue.² Thus, because the date of patent issuance also corresponds to its publication date, the issuance of a U.S. patent meets the MPEP language of a "U.S. patent published within the year."

Additionally, if a U.S. patent is later found invalid or the patent rights otherwise extinguished, the patent document itself nevertheless remains a published document readily available to the public. Such a patent is "published" by the USPTO on the day the patent is granted. Moreover, such a document remains "published" irrespective of the status of the patent rights associated therewith.

Final Rejection

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

² In fact, some countries do not publish patent documents concurrent with the granting of patent rights, but instead delay publication for a limited time after the granting of patent rights. In those situations, the invention is "patented" when the patent rights become fixed despite no associated publication. This is an issue in determining potential §102(d) prior art.

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Conclusion

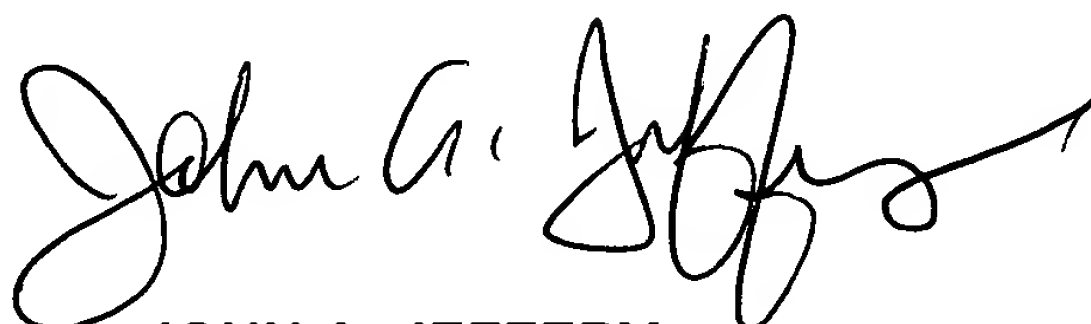
Any inquiry concerning this or earlier communications from the examiner should be directed to John A. Jeffery at telephone number (703) 306-4601 or fax (703) 305-3463. The examiner can normally be reached on Monday-Thursday from 7:00 AM to 4:30 PM EST. The examiner can also be reached on alternate Fridays.

The fax phone numbers for the organization where this application or proceeding is assigned are:

Before Final	(703) 872-9302
After Final	(703) 872-9303
Customer Service	(703) 872-9301

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0861.

A handwritten signature in black ink, appearing to read "John A. Jeffery", with a stylized flourish at the end.

**JOHN A. JEFFERY
PRIMARY EXAMINER**

5/19/03